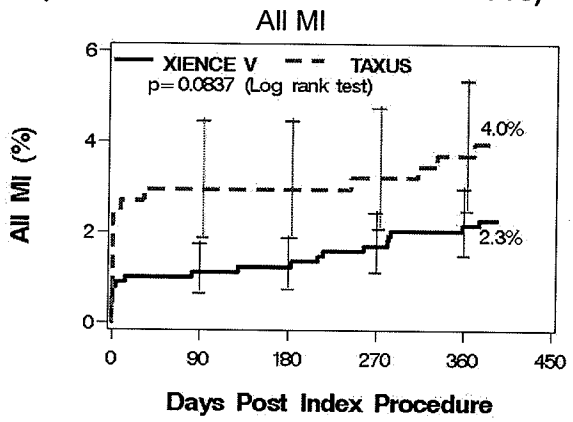
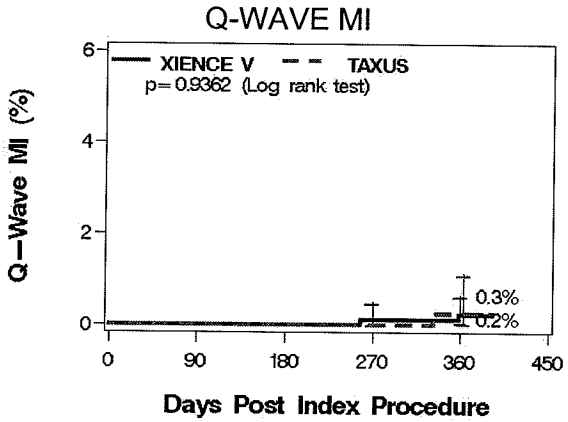
Pooled analyses of the rates of MIs through 1 year are shown in Figure 9.4-3.

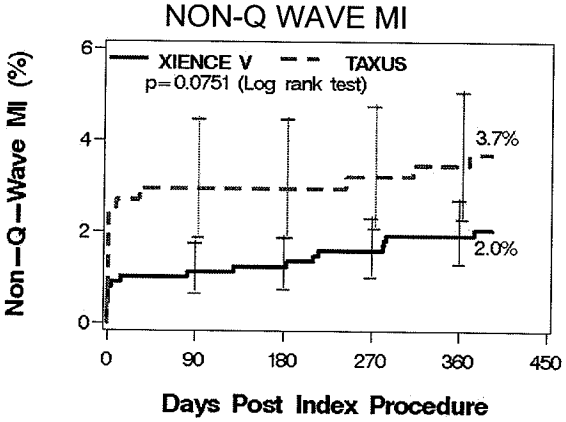
Figure 9.4-3: Kaplan Meier Hazard Curves for Time to First MI Event through 393 Days (Pooled SPIRIT II and SPIRIT III RCTs)



Note: P-value is not adjusted for multiplicity and is meant for descriptive purposes only.



Note: P-value is not adjusted for multiplicity and is meant for descriptive purposes only.



Note: P-value is not adjusted for multiplicity and is meant for descriptive purposes only.

9.4.1 Stent Thrombosis in SPIRIT II and SPIRIT III Pooled Analysis

The results for the pooled analysis rates of stent thrombosis at one year are shown below in Figure 9.4.1-1. Rates were low for both treatments in this pooled analysis and consistent with the published literature[10]. The rates of stent thrombosis were evaluated based on the SPIRIT II and III protocol defined definition and the ARC definition for definite + probable thrombosis (see definitions above in Section 8.2). These data are presented in table 9.4.1-1.

Table 9.4.1-1 Pooled Results for Stent Thrombosis through 1 year (SPIRIT II and SPIRIT III RCT)

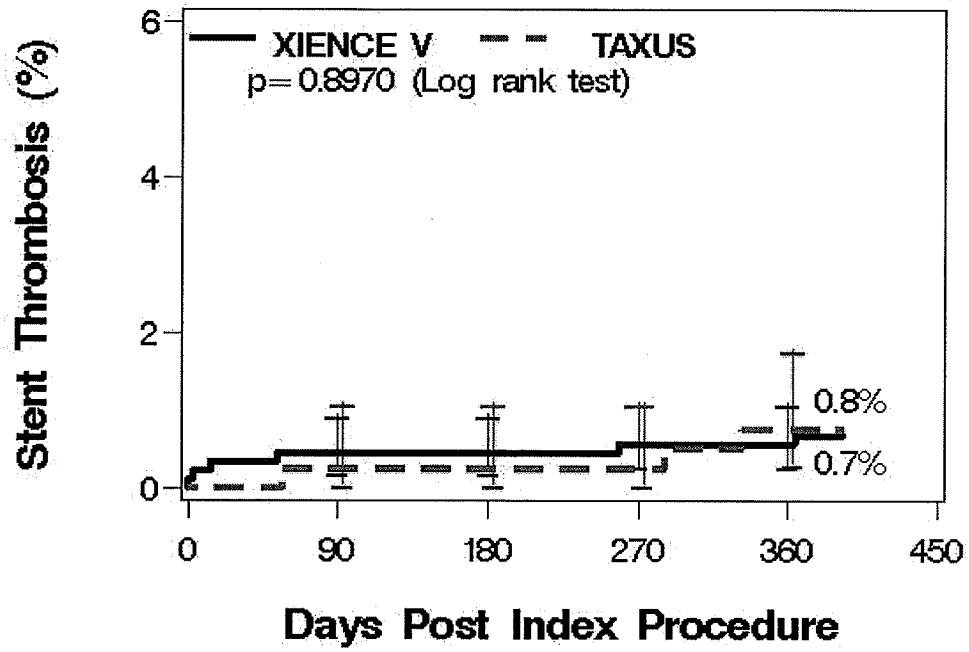
	XIENCE V (N=892)	95% CI[1]	TAXUS (N=410)	95% CI[1]
0 - 30 days				
Protocol	0.3% (3/890)	[0.07%, 0.98%]	0.0% (0/407)	[0.00%, 0.90%]
ARC (definite + probable)	0.4% (4/890)	[0.12%, 1.15%]	0.2% (1/407)	[0.01%, 1.36%]
31 days – 1 year				
Protocol	0.3% (3/866)	[0.07%, 1.01%]	0.8% (3/394)	[0.16%, 2.21%]
ARC (definite + probable)	0.3% (3/867)	[0.07%, 1.01%]	0.8% (3/394)	[0.16%, 2.21%]
0 – 1 year				
Protocol	0.7% (6/867)	[0.25%, 1.50%]	0.8% (3/394)	[0.16%, 2.21%]
ARC (definite + probable)	0.8% (7/868)	[0.32%, 1.65%]	0.8% (3/394)	[0.16%, 2.21%]

Note: timeframe for 1 year includes the follow-up window (365 + 28 days)
[1] By Clopper-Pearson Exact Confidence Interval

[10] Ellis SG CA, Grube E, Popma J, Koglin J, Dawkins KD, Stone GW. Incidence, timing, and correlates of stent thrombosis with the polymeric paclitaxel drug-eluting stent: a TAXUS II, IV, V, and VI meta-analysis of 3,445 patients followed for up to 3 years. *J Am Coll Cardiol.* 2007;49:1043-1051.

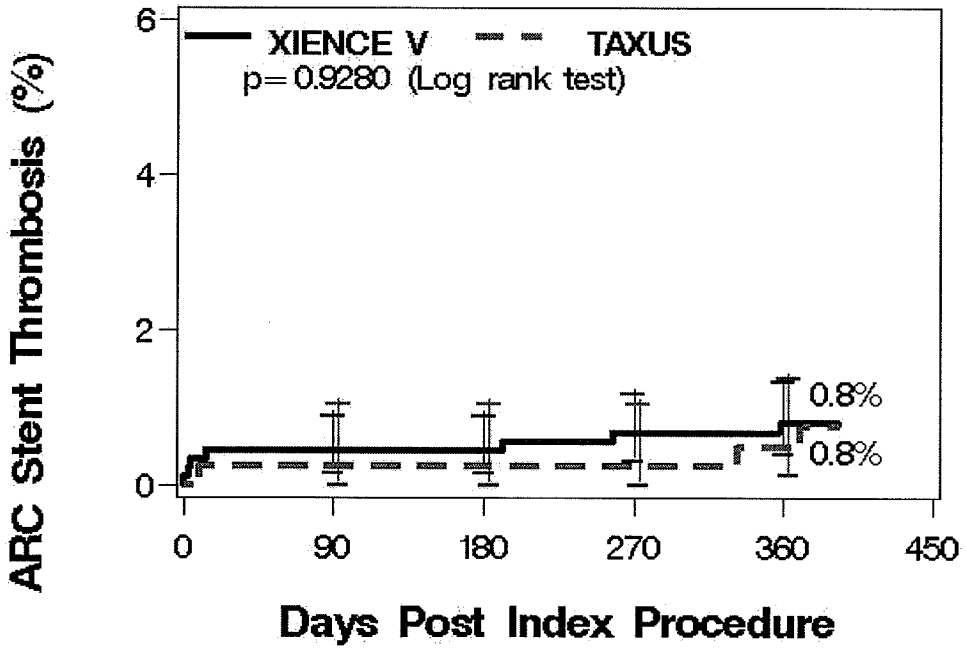
Figure 9.4.1-1: Kaplan Meier Hazard Curves for Time to First Stent Thrombosis Event through 393 Days (Pooled SPIRIT II and SPIRIT III RCTs)

Protocol Defined Stent Thrombosis



Note: P-value is not adjusted for multiplicity and is meant for descriptive purposes only.

ARC DEFINED STENT THROMBOSIS (DEFINITE + PROBABLE)



Note: P-value is not adjusted for multiplicity and is meant for descriptive purposes only.

9.4.2 Diabetics in SPIRIT II and SPIRIT III Pooled Analysis

Diabetic subjects comprise an important subject subgroup that is at increased risk for cardiovascular morbidity and mortality. Although diabetic subjects were included in the SPIRIT family of trials, there were no pre-specified hypotheses or trial features that warrant a specific labeled indication for the use of the XIENCE V stent in diabetic individuals.

Table 9.4.2-1 shows the clinical outcomes through 1 year in subjects pooled from SPRIT II and III. The randomization was stratified by history of diabetes to assure a balance between the XIENCE V and TAXUS treatment arms. In XIENCE V patients, there were numerically higher event rates in diabetics compared with non-diabetics. The event rates for TAXUS in diabetics were lower than the event rates for TAXUS non-diabetics. Given the relatively small sample size of the diabetic population and potential for confounding variables, no conclusions can be drawn from these post-hoc analyses.

Table 9.4.2-1: Clinical Results in Diabetics and Non-Diabetics through 1 year (SPIRIT II and SPIRIT III RCT Pooled Population)

	Non-Diabetics XIENCE V (N=643)	Non-Diabetics TAXUS (N=296)	All Diabetics XIENCE V (N=249)	All Diabetics TAXUS (N=110)
TLR	2.5% (16/629)	7.6% (22/290)	4.5% (11/244)	1.0% (1/104)
TVR(CABG/PCI), non TL	2.5% (16/629)	4.1% (12/290)	3.3% (8/244)	2.9% (3/104)
All Death	1.0% (6/631)	2.4% (7/291)	2.0% (5/246)	0.0% (0/104)
Cardiac Death	0.3% (2/631)	1.4% (4/291)	1.2% (3/246)	0.0% (0/104)
Non-Cardiac Death	0.6%(4/631)	1.0%(3/291)	0.8%(2/246)	0.0% (0/104)
MI	1.4% (9/629)	4.5% (13/290)	4.5% (11/244)	2.9% (3/104)
Cardiac Death or MI	1.7% (11/629)	5.2% (15/290)	5.3% (13/244)	2.9% (3/104)
Stent Thrombosis				
Protocol defined	0.5% (3/627)	1.0% (3/287)	1.3% (3/240)	0.0% (0/104)
ARC definite + probable	0.3% (2/627)	0.7% (2/287)	2.1% (5/241)	1.0% (1/104)

Table 9.4.2-2: Clinical Results in Diabetics through 1 year (SPIRIT II and SPIRIT III RCT Pooled Population – XIENCE V Subjects)

	Non-Diabetics (N=643)	All Diabetics (N=249)	Insulin-Dependent Diabetics (N=63)	Non-Insulin-Dependent Diabetics (N=186)
TLR	2.5% (16/629)	4.5% (11/244)	6.5% (4/62)	3.8% (7/182)
TVR(CABG/PCI), non TL	2.5% (16/629)	3.3% (8/244)	1.6% (1/62)	3.8% (7/182)
All Death	1.0% (6/631)	2.0% (5/246)	3.2% (2/63)	1.6% (3/183)
Cardiac Death	0.3% (2/631)	1.2% (3/246)	1.6% (1/63)	1.1% (2/183)
Non-Cardiac Death	0.6% (4/631)	0.8%(2/246)	1.6% (1/63)	0.5% (1/183)
MI	1.4% (9/629)	4.5% (11/244)	9.7% (6/62)	2.7% (5/182)
Cardiac Death or MI	1.7% (11/629)	5.3% (13/244)	9.7% (6/62)	3.8% (7/182)
Stent Thrombosis				
Protocol defined	0.5% (3/627)	1.3% (3/240)	1.6% (1/61)	1.1% (2/179)
ARC definite + probable	0.3% (2/627)	2.1% (5/241)	1.6% (1/61)	2.2% (4/180)

9.4.3 Dual Vessel treatment in SPIRIT II and SPIRIT III Pooled Analysis

Subjects requiring treatment in more than one vessel comprise a subgroup that is at increased risk for cardiovascular events compared with single vessel disease patients. Although subjects requiring both single and dual vessel treatment were included in the SPIRIT family of trials, there were no pre-specified hypothesis or trial features that warrant a specific labeled indication for the use of the XIENCE V stent in dual vessel individuals.

Table 9.4.3-1 shows the clinical outcomes through 1 year in subjects pooled from SPRIT II and III. The randomization was stratified by the number of vessels treated to assure a balance between the XIENCE V and TAXUS treatment arms. Numerically lower event rates were observed for XIENCE V and TAXUS in single compared to dual vessel treatment. However, given the small sample size for dual vessel treatment, no conclusions can be drawn from this post-hoc analysis.

Table 9.4.3-1: Clinical Results in Single and Dual Vessel Treatment through 1 year (SPIRIT II and SPIRIT III RCT Pooled Population)

	Single Vessel XIENCE V (N=752)	Single Vessel TAXUS (N=344)	Dual Vessel XIENCE V (N=140)	Dual Vessel TAXUS (N=65)
TLR	2.9% (21/735)	4.5% (15/333)	4.3% (6/138)	12.5% (8/64)
TVR(CABG/PCI), non TLR	2.3% (17/735)	2:1% (7/333)	5.1% (7/138)	12.5% (8/64)
All Death	1.5% (11/739)	1.2% (4/333)	0.0% (0/138)	4.6% (3/65)
Cardiac Death	0.7% (5/739)	0.6% (2/333)	0.0% (0/138)	3.1% (2/65)
Non-Cardiac Death	0.8% (6/739)	0.6% (2/333)	0.0% (0/138)	1.5% (1/65)

	Single Vessel XIENCE V (N=752)	Single Vessel TAXUS (N=344)	Dual Vessel XIENCE V (N=140)	Dual Vessel TAXUS (N=65)
MI	1.9% (14/735)	3.0% (10/333)	4.3% (6/138)	9.4% (6/64)
Cardiac Death or MI	2.4% (18/735)	3.3% (11/333)	4.3% (6/138)	10.9% (7/64)
Stent Thrombosis				
Protocol defined	0.3% (2/729)	0.6% (2/332)	2.9% (4/138)	1.6% (1/62)
ARC definite + probable	0.5% (4/730)	0.6% (2/332)	2.2% (3/138)	1.6% (1/62)

10.0 INDIVIDUALIZATION OF TREATMENT

The risks and benefits should be considered for each patient before using the PROMUS stent. Patient selection factors to be assessed should include a judgment regarding risk of long-term antiplatelet therapy. Stenting is generally avoided in those patients at a heightened risk of bleeding (e.g., patients with recently active gastritis or peptic ulcer disease) in which anticoagulation therapy would be contraindicated.

Antiplatelet drugs should be used in combination with the PROMUS stent. Physicians should use information from the SPIRIT Clinical trials, coupled with current drug eluting stent (DES) literature and the specific needs of individual patients to determine the specific antiplatelet/anticoagulation regimen to be used for their patients in general practice. See also 5.2 – Precautions, Pre- and Post-Procedure Antiplatelet Regimen, Section 5.6 – Precautions, Use in Special Populations and Section 5.7 – Precautions, Lesion/Vessel Characteristics.

Premorbid conditions that increase the risk of poor initial results or the risks of emergency referral for bypass surgery (diabetes mellitus, renal failure, and severe obesity) should be reviewed.

11.0 PATIENT COUNSELING AND PATIENT INFORMATION

Physicians should consider the following in counseling patients about this product:

- Discuss the risks associated with stent placement.
- Discuss the risks associated with an everolimus-eluting stent.
- Discuss the risks of early discontinuation of the antiplatelet therapy.
- Discuss the risks of late stent thrombosis with DES use in higher risk patient subgroups.
- Discuss the risk/benefit issues for this particular patient.
- Discuss alteration to current life-style immediately following the procedure and over the long term.

The following patient materials are available for this product:

- A Patient Information Guide which includes information on coronary artery disease, the implant procedure and the PROMUS Everolimus-Eluting Coronary Stent System (provided to physician, on-line at www.bostonscientific.com/promus, or by calling customer service 1-888-272-1001).
- A Stent Implant Card that includes both patient information and stent implant information (provided in package)

12.0 HOW SUPPLIED

Sterile: This device is sterilized with ethylene oxide gas, non-pyrogenic. It is intended for single use only. Do not resterilize. Do not use if the package is opened or damaged.

Contents: One (1) PROMUS Everolimus-Eluting Coronary Stent System, one (1) Flushing tool, (for the PROMUS EECSS Rapid Exchange (RX) Stent System), one (1) Stent Implant Card, one (1) Patient Information Guide.

Storage: Store in a dry, dark, cool place. Protect from light. Do not remove from carton until ready for use. Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

13.0 OPERATOR'S INSTRUCTIONS

13.1 Inspection Prior to Use

- Carefully inspect the sterile package before opening and check for damage to the sterile barrier. Do not use if the integrity of the sterile package has been compromised.
- Do not use after the "Use By" date.
- Tear open the foil pouch and remove the inner pouch. **Note: the outside of the inner pouch is NOT sterile.** Open the inner pouch and pass or drop the product into the sterile field using an aseptic technique.
- Prior to using the PROMUS Everolimus-Eluting Coronary Stent System, carefully remove the system from the package and inspect for bends, kinks, and other damage. Verify that the stent does not extend beyond the radiopaque balloon markers. Do not use if any defects are noted. However, **do not manipulate, touch, or handle the stent** with your fingers, which may cause coating damage, contamination or stent dislodgement from the delivery balloon.

Note: At any time during use of the PROMUS Rapid Exchange (RX) EECSS, if the stainless steel proximal shaft has been bent or kinked, do not continue to use the catheter.

13.2 Materials Required

- Appropriate guiding catheter(s). See Table 1-1, PROMUS Stent System Product Description
- 2 – 3 syringes (10 – 20 ml)
- 1,000 u/500 ml Heparinized Normal Saline (HepNS)
- 0.014 inch (0.36 mm) x 175 cm (minimum length) guide wire
- Rotating hemostatic valve with appropriate minimum inner diameter [0.096 inch (2.44 mm)]
- 60% contrast diluted 1:1 with heparinized normal saline
- Inflation device

- Pre-deployment dilatation catheter
- Three-way stopcock
- Torque device
- Guide wire introducer
- Appropriate arterial sheath
- Appropriate anticoagulation and antiplatelet drugs

13.3 Preparation

13.3.1 Packaging Removal

Note: The foil pouch is not a sterile barrier. The inner header bag (pouch) within the foil pouch is the sterile barrier. Only the contents of the inner pouch should be considered sterile. The outside surface of the inner pouch is NOT sterile.

1. Carefully remove the delivery system from its protective tubing for preparation of the delivery system. When using a Rapid Exchange (RX) system, do not bend or kink the hypotube during removal.

2. Remove the product mandrel and protective stent sheath by grasping the catheter just proximal to the stent (at the proximal balloon bond site), and with the other hand, grasp the stent protector and gently remove distally. If unusual resistance is felt during product mandrel and stent sheath removal, do not use this product and replace with another. Follow product returns procedure for the unused device.

13.3.2 Guide Wire Lumen Flush

1. Over the Wire (OTW) only: Flush the guide wire lumen with HepNS until fluid exits the distal end of the delivery system.

2. Rapid Exchange (RX) only: Flush the guide wire lumen with HepNS using the flushing tool supplied with the product. Insert the flushing tool into the tip of the catheter and flush until fluid exits the guide wire exit notch.

Note: Avoid manipulation of the stent while flushing the guide wire lumen, as this may disrupt the placement of the stent on the balloon.

13.3.3 Delivery System Preparation

1.	Prepare an inflation device/syringe with diluted contrast medium.
2.	Attach an inflation device/syringe to the stopcock; attach it to the inflation port of the product. Do not bend the product hypotube when connecting to the inflation device/syringe.
3.	With the tip down, orient the delivery system vertically.
4.	Open the stopcock to delivery system; pull negative for 30 seconds; release to neutral for contrast fill.
5.	Close the stopcock to the delivery system; purge the inflation device/syringe of all air.
6.	Repeat steps 3 through 5 until all air is expelled. If bubbles persist, do not use the product.
7.	If a syringe was used, attach a prepared inflation device to stopcock.
8.	Open the stopcock to the delivery system.
9.	Leave on neutral
Note: If air is seen in the shaft, repeat Delivery System Preparation steps 3 through 5 to prevent uneven stent expansion.	

13.4 Delivery Procedure

1. Prepare the vascular access site according to standard practice.

2. **Pre-dilate the lesion with a PTCA catheter of appropriate length and diameter for the vessel/lesion to be treated.** Limit the longitudinal length of pre-dilatation by the PTCA balloon to avoid creating a region of vessel injury that is outside the boundaries of the PROMUS Stent.

Note: The labeled stent diameter refers to expanded stent inner diameter.

3. Maintain neutral pressure on the inflation device attached to the delivery system. Open the rotating hemostatic valve as wide as possible.

4. Backload the delivery system onto the proximal portion of the guide wire while maintaining guide wire position across the target lesion.

5. Carefully advance the delivery system into the guiding catheter and over the guide wire to the target lesion. When using a Rapid Exchange (RX) system be sure to keep the hypotube straight. Ensure guiding catheter stability before advancing the stent system into the coronary artery.

Note: If unusual resistance is felt before the stent exits the guiding catheter, do not force passage. Resistance may indicate a problem and the use of excessive force may result in stent damage or dislodgement. Maintain guide wire placement across the lesion and remove the delivery system and guiding catheter as a single unit.

6. Advance the delivery system over the guide wire to the target lesion under direct fluoroscopic visualization. Utilize the radiopaque balloon markers to position the stent across the lesion. Perform angiography to confirm stent position. If the position of the stent is not optimal, it should be carefully repositioned or removed (see Section 5.14 – Precautions, Delivery System Removal). The balloon markers indicate both the stent edges and the balloon shoulders. Expansion of the stent should not be undertaken if the stent is not properly positioned in the target lesion.

Note: Should **any resistance** be felt **at any time** during either lesion access or removal of the delivery system post-stent implantation, **remove the entire system as a single unit.** See Section 5.14 – Precautions, Delivery System Removal for specific delivery system removal instructions.

7. Tighten the rotating hemostatic valve. The stent is now ready to be deployed.

13.5 Deployment Procedure

CAUTION: Refer to Table 14-1: Typical PROMUS Stent Compliance for in vitro stent inner diameter, nominal pressure, and RBP.

1. Prior to deployment, reconfirm the correct position of the stent relative to the target lesion using the radiopaque balloon markers.

2. Deploy the stent slowly by pressurizing the delivery system in 2 atm increments, every 5 seconds, until stent is completely expanded. Accepted practice generally targets an initial deployment pressure that would achieve a stent inner diameter ratio of about 1.1 times the reference vessel diameter (see Table 14-1). Maintain pressure for 30 seconds. If necessary, the delivery system can be repressurized or further pressurized to assure complete apposition of the stent to the artery wall. **Do not exceed the labeled rated burst pressure (RBP) of 16 atm (1.62 MPa).**

3. Fully cover the entire lesion and balloon treated area (including dissections) with the PROMUS stent, allowing for adequate stent coverage into healthy tissue proximal and distal to the lesion.

4. Deflate the balloon by pulling negative on the inflation device for 30 seconds. Confirm complete balloon deflation before attempting to move the delivery system. If unusual resistance is felt during stent delivery system withdrawal, pay particular attention to guiding catheter position.

5. Confirm stent position and deployment using standard angiographic techniques. For optimal results, the entire stenosed arterial segment should be covered by the stent. Fluoroscopic visualization during stent expansion should be used in order to properly judge the optimum expanded stent diameter as compared to the proximal and distal coronary artery diameter(s). Optimal expansion requires that the stent be in full contact with the artery wall. Stent wall contact should be verified through routine angiography or intravascular ultrasound (IVUS).

6. If the deployed stent size is still inadequate with respect to reference vessel diameter, a larger balloon may be used to further expand the stent. If the initial angiographic appearance is sub-optimal, the stent may be further expanded using a low profile, high pressure, non-compliant balloon dilatation catheter. If this is required, the stented segment should be carefully recrossed with a prolapsed guide wire to avoid disrupting the stent geometry. Deployed stents should not be left under-dilated.

CAUTION: Do not dilate the stent beyond the following limits.

Nominal Stent Diameter	Dilatation Limit
2.5 mm to 3.0 mm	**3.5 mm**
3.5 mm to 4.0 mm	**4.5 mm**

7. If more than one PROMUS stent is needed to cover the lesion and balloon treated area, it is suggested that, to avoid the potential for gap restenosis, the stents be adequately overlapped. To ensure that there are no gaps between

stents the balloon marker bands of the second PROMUS stent should be positioned inside the deployed stent prior to expansion.

8. Reconfirm stent position and angiographic results. Repeat inflations until optimal stent deployment is achieved.

13.6 Removal Procedure

1. Deflate the balloon by pulling negative pressure on the inflation device for 30 seconds. Confirm complete balloon deflation before attempting to move the delivery system. If unusual resistance is felt during stent delivery system withdrawal, pay particular attention to the guiding catheter position.

2. Fully open the rotating hemostatic valve.

3. While maintaining the guide wire position and negative pressure on the inflation device, withdraw the delivery system.

Note: Should **any resistance** be felt **at any time** during either lesion access or removal of the delivery system post-stent implantation, the entire system should be **removed as a single unit**. See Section 5.14 – Precautions, Delivery System Removal for specific delivery system removal instructions.

4. Tighten the rotating hemostatic valve.

5. Repeat angiography to assess the stented area. If post-dilatation is necessary, ensure that the final stent diameter matches the reference vessel diameter. **Assure that the stent is not under-dilated.**

13.7 Post-Deployment Dilatation of Stent Segments

1. All efforts should be taken to assure that the stent is not underdilated. If the deployed stent size is still inadequate with respect to the vessel diameter, or if full contact with the vessel wall is not achieved, a larger balloon may be used to expand the stent further. The stent may be further expanded using a low profile, high pressure, and non-compliant balloon catheter. If this is required, the stented segment should be recrossed carefully with a prolapsed guide wire to avoid dislodging the stent. The balloon should be centered within the stent and should not extend outside of the stented region.

CAUTION: Do not dilate the stent beyond the following limits.

Nominal Stent Diameter	Dilatation Limit
2.5 mm to 3.0 mm	**3.5 mm**
3.5 mm to 4.0 mm	**4.5 mm**

14.0 *IN VITRO* COMPLIANCE INFORMATION

Table 14-1: Typical PROMUS Stent Compliance
Nominal pressure for each diameter indicated by bold font.

Pressure		Stent ID (mm) by System Size				
(atm)	(MPa)	2.5 mm	2.75 mm	3.0 mm	3.5 mm	4.0 mm
8	0.81	**2.46**	**2.74**	2.90	3.46	3.86
9	0.91	2.52	2.81	**2.97**	**3.55**	**3.95**
10	1.01	2.58	2.87	3.04	3.63	4.03
11	1.11	2.63	2.92	3.10	3.69	4.10
12	1.22	2.68	2.97	3.15	3.75	4.17
13	1.32	2.72	3.01	3.19	3.80	4.23
14	1.42	2.75	3.05	3.23	3.84	4.28
15	1.52	2.78	3.08	3.26	3.89	4.33
16 (RBP)*	1.62	2.81	3.11	3.30	3.93	4.37
17	1.72	2.84	3.14	3.33	3.97	4.42
18	1.82	2.87	3.18	3.36	4.00	4.46

Note: These nominal data are based on *in vitro* testing at 37°C and do not take into account lesion resistance.
Ensure full deployment of the stent (see Section 13.5, Operator's Instructions, Deployment Procedure) and confirm the stent sizing angiographically.
*Do not exceed the rated burst pressure (RBP).

15.0 REUSE PRECAUTION STATEMENT

Do not use if sterile barrier is damaged. If damage is found call your Boston Scientific, Cardiac Therapies representative.

For single patient use only. Do not reuse, reprocess or resterilize.

16.0 PATENTS

This product and its use are protected by one or more of the following patents. United States, 4,571,240; 4,573,470; 4,581,017; 4,582,181; 4,597,755; 4,616,653; 4,619,263; 4,638,805; 4,641,654; 4,661,094; 4,664,113; 4,692,200; 4,748,982; 4,771,776; 4,771,777; 4,771,778; 4,775,371; 4,782,834; 4,790,315; 4,793,350; 4,821,722; 4,877,031; 4,892,519; 4,938,220; 4,940,062; 4,964,409; 4,976,720; 4,981,478; 4,998,917; 4,998,923; 5,002,532; 5,002,560; 5,003,989; 5,034,001; 5,040,548; 5,042,985; 5,046,503; 5,061,273; 5,090,959; 5,135,535; 5,137,513; 5,154,725; 5,159,937; 5,176,661; 5,180,368; 5,195,971; 5,234,002; 5,242,394; 5,242,396; 5,256,143; 5,263,963; 5,279,562; 5,290,230; 5,300,025; 5,300,085; 5,316,706; 5,318,527; 5,324,259; 5,334,154; 5,342,621; 5,346,505; 5,348,537; 5,350,395; 5,391,172; 5,397,305; 5,409,495; 5,411,476; 5,415,637; 5,421,955; 5,423,755; 5,423,885; 5,437,083; 5,441,515; 5,443,458; 5,443,500; 5,451,209; 5,451,233; 5,456,667; 5,458,605; 5,458,613; 5,458,615; 5,476,505; 5,480,383; 5,496,275; 5,496,346; 5,498,240; 5,507,301; 5,507,768; 5,507,795; 5,514,154; 5,516,336; 5,525,388; 5,533,968; 5,542,925; 5,546,646; 5,549,551; 5,549,554; 5,554,120; 5,554,121; 5,556,413; 5,558,643; 5,565,523; 5,573,508; 5,573,509; 5,591,197; 5,593,434; 5,603,721; 5,605,696; 5,607,444; 5,618,299; 5,629,077; 5,632,754; 5,632,840; 5,636,641; 5,637,089; 5,637,113; 5,649,977; 5,681,346; 5,693,015; 5,695,506; 5,700,286; 5,707,385; 5,709,658; 5,725,549; 5,728,158; 5,735,893; 5,743,875; 5,747,591; 5,749,888; 5,759,192; 5,769,868; 5,780,807; 5,782,855; 5,807,355; 5,816,923; 5,830,181; 5,849,846; 5,868,706; 5,868,767; 5,891,090; 5,902,290; 5,931,819; 5,989,218; 5,993,460; 6,013,054; 6,013,069; 6,013,728; 6,017,364; 6,019,777; 6,027,475; 6,036,707; 6,036,715;

6,056,776; 6,059,748; 6,059,770; 6,061,588; 6,117,106; 6,126,634; 6,126,635; 6,129,707; 6,131,266; 6,136,011; 6,139,525; 6,156,047; 6,165,152; 6,165,292; 6,179,810; 6,193,686; 6,200,325 B1; 6,206,852; 6,217,547; 6,221,425; 6,224,803; 6,238,376; 6,248,092; 6,251,094; 6,273,911; 6,296,655; 6,299,595; 6,309,412; 6,369,355; 6,419,693; 6,432,133; 6,482,166; 6,485,511; 6,488,655; 6,488,694; 6,527,789; 6,561,788; 6,572,813; 6,575,958; 6,575,993; 6,620,193; 6,629, 991; RE 33,166; RE 34,564.
Other U.S. patents pending. Foreign patents issued and pending.

XIENCE V, MULTI-LINK VISION, and MULTI-LINK MINI VISION are trademarks of the Abbott Group of Companies.

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17.0 WARRANTY

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Graphical Symbols for Medical Device Labeling

Manufacturer	REF Catalogue Number	F French Size
Do not reuse, do not resterilize	STERILE EO Sterilized using Ethylene Oxide	Consult Instructions for Use
Use By	LOT Batch Code	Date of Manufacture
Guiding Catheter	PYROGEN Non-Pyrogenic	Contents (Numeral represents quantity of units inside)
Inner Diameter		

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News Releases

Boston Scientific Announces FDA Approval for PROMUS™ Everolimus-Eluting Coronary Stent System

Boston Scientific only company to offer choice of two distinct drugs on separate drug-eluting stent platforms

PRNewswire-FirstCall
NATICK, Mass.
(NYSE:BSX)
Jul 02, 2008

NATICK, Mass., July 2 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced that the U.S. Food and Drug Administration (FDA) has approved the PROMUS™ Everolimus-Eluting Coronary Stent System for the treatment of coronary artery disease. The PROMUS Stent is a private-labeled XIENCE™ V Everolimus-Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific under an agreement executed prior to the 2006 acquisition of the former Guidant Corporation by Boston Scientific. FDA approval clears the way for Boston Scientific to launch the PROMUS Stent immediately in the U.S.

The PROMUS Stent expands Boston Scientific's drug-eluting stent (DES) portfolio, which includes the TAXUS® Express2® Paclitaxel-Eluting Coronary Stent System (in the U.S. and international markets) and the TAXUS® Liberte® Paclitaxel-Eluting Coronary Stent System (in international markets), making Boston Scientific the only company to offer physicians the choice of two distinct drugs (paclitaxel and everolimus) on separate DES platforms.

"The PROMUS Stent has shown outstanding deliverability, low late loss and the potential to reduce the need for re-interventions," said Ted Feldman, M.D., F.S.C.A.I., Director of the Cardiac Catheterization Laboratory at Evanston Northwestern Healthcare in Evanston, Illinois. "These benefits will make the PROMUS Stent an attractive new treatment option for U.S. physicians and their patients."

"FDA approval of the PROMUS Stent fulfills Boston Scientific's promise of an unprecedented two-drug strategy - two distinct drugs on two highly deliverable stent platforms," said Jim Tobin, President and Chief Executive Officer of Boston Scientific. "The PROMUS Stent complements our broad DES portfolio and further reinforces Boston Scientific's leadership in the DES market, as well as our commitment to continued innovation and improved patient outcomes."

The next-generation PROMUS Stent is a highly deliverable stent made from cobalt chromium, which allows for thinner struts without sacrificing strength or visibility. The SPIRIT clinical trials indicate that the combination of the polymer/stent platform and the controlled release of the everolimus drug results in excellent deliverability, a strong safety profile, low levels of late loss and improved efficacy, making the PROMUS (XIENCE V) Stent a valuable addition to the U.S. drug-eluting stent market.

Boston Scientific's PROMUS Stent and Abbott's XIENCE V Stent are identical products sold by the respective companies under different brand names. The PROMUS (XIENCE V) Stent is indicated for improving coronary luminal diameter in patients with symptomatic heart disease due to de novo native coronary artery lesions (up to 28 mm long) with reference vessel diameter of 2.5 to 4.0 mm.

As a result of agreements related to its acquisition of Guidant in 2006, Boston Scientific shares the rights to everolimus-eluting stent technologies with Abbott, including the XIENCE V Everolimus-Eluting Coronary Stent System (marketed by Boston Scientific as

the PROMUS Stent). The Company will continue to market its internally developed paclitaxel-eluting TAXUS Stent Systems, which have been the worldwide DES market leaders, implanted in more than four million people. Boston Scientific is also developing paclitaxel- eluting, everolimus-eluting and bare-metal versions of its third-generation Element™ Stent, which uses a unique platinum-enriched alloy.

The PROMUS Stent is currently for sale in Europe and certain other international markets. TAXUS and PROMUS are trademarks of Boston Scientific Corporation or its affiliates. XIENCE is a trademark of the Abbott Laboratories group of companies. SPIRIT is sponsored by Abbott. The TAXUS Liberte Paclitaxel-Eluting Coronary Stent System is pending approval by the FDA and is not available for sale in the United States.

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: http://www.bostonscientific.com/.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward- looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding our product performance, regulatory approval of our products, competitive offerings, our growth strategy, and our market position. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; intellectual property; litigation; financial market conditions; and, future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A - Risk Factors in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A - Risk Factors in Quarterly Reports on Form 10-Q we have filed or will file thereafter. We disclaim any intention or obligation to publicly update or revise any forward- looking statements to reflect any change in our expectations or in events, conditions, or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this document.

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